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510(k) Summary

PRIME ECG™ System

Common/Classification Name: Electrocardiograph as classified under 21 CFR 870.2340

Meridian Medical Technologies
10240 Old Columbia Road
Columbia, MD 21046

Telephone: 410-309-6830
Fax: 410-309-1475

Contact: Jamil F. LaHam
General Manager, Cardiopulmonary Systems

Prepared: July 25, 2001

A. Legally Marketed Predicate Devices

The PRIME ECG System is substantially equivalent to the Hewlett Packard M1700A cleared under K911139. Both systems have the same intended use, which is to record electrocardiographic signals.

B. Device Description

The PRIME ECG System uses an 80-lead disposable electrode array referred to as a vest or harness. The electrodes are screen-printed onto a clear plastic substrate. The section of the vest applied to the anterior side of the patient (anterior harness, applied to chest area) contains channels 1 to 55 and 59 to 64. The section applied to the posterior side of the patient (posterior harness, applied to the patient's back) contains channels 65 to 80. Channels 56, 57 and 58 are applied to the right arm, left arm and left leg, respectively.

Signals are conducted along pathways that are also printed, eliminating the need for conventional lead wires. The electrode array or "vest" features pre-applied gel to assure good conductivity and secure attachment. Anatomical markers provide for consistent location on different size patients. The vest can be applied in less than 5 minutes.

An 80 channel recording device is attached to the vest by means of two spring clips that interface with the printed lead lines. This means that 80 separate electrical signals are collected and stored.

The system measures the ECG recordings simultaneously for all 80 channels. For practical reasons only eight channels are displayed at one time, so the operator may scroll through 10 screens to visualize all active channels. The system contains an algorithm that identifies (with color, words and symbols) any individual electrode that may be suspect, allowing the operator to make adjustments before recording. Once satisfied, the operator activates the recording and the system retains 10.0 seconds of data. If the recording contains any poor signals, the algorithm alerts the operator who must determine whether to accept the recording. The number of poor quality leads may not exceed 6 on the anterior harness. If the signals from any 2 adjacent electrodes, or any posterior electrode, are bad, the maps are not accepted. It is possible for the operator to accept a recording which contains channels that have low quality, but resulting maps contain the legend "Unacceptable Quality" and each poor quality channel is marked in red.

Because the electrode vest covers most of the torso, electrode locations include those for a standard 12-lead ECG. This means that among the 80 leads individual locations are consistent with required placement necessary to result in a conventional 12-lead recording and display. There is a user-selected option for displaying these leads, (e.g., the channels are automatically selected and displayed which correspond to a Lead II ECG), although the operator may designate specific electrodes to reflect preferred locations for display.

Once the 80-lead recording is accepted, the system creates a series of isopotential and isointegral images (maps) for specific segments of a single beat. Measuring signal strength at a specific time interval of the beat creates Isopotential maps. The resulting strengths and locations of these signals are plotted against an "unwrapped" image of the torso. For example, the unwrapped torso image can be oriented with an x and y axis. At a given point in time, an voltage measurement in millivolts is collected at each location (x,y). This voltage can be plotted along the z axis. If lines are drawn on this plot to connect points with the same voltage z, isopotential contour maps are created. Isopotential maps can be created at any point in time during the cardiac cycle to reflect the cyclic polarization and repolarization of the heart.

Isopotential maps reflect what is happening to the heart at a selected point in time, while isointegral maps are an attempt to provide a look at what is happening over the cycle, as a body surface distribution of the ventricular gradient. At each location (x,y) the potential z changes over the time of the cardiac cycle. Integrating the areas under the QRST of each lead gives the gradient at each point. The gradient at each point is then mapped. Joining points on the plot with the same calculated gradient produces the isointegral contour map. The isointegral map allows evaluation of repolarization properties.

C. Indications for Use

The PRIME ECG is indicated for the recording of electrocardiographic signals on the body surface.

D. Substantial Equivalence Summary

The PRIME ECG conforms to EC 11 standard for diagnostic ECG systems and IEC 60601 standards for electrical safety. It is substantially equivalent to marketed ECG systems.

In addition, a clinical study was performed that demonstrated that the PRIME ECG System provides information enabling improved diagnosis of AMI upon presentation to the ER compared to standard 12 lead ECG systems.

E. Technological Characteristics

See Device Description, above.

F. Testing

The entire system has been tested to demonstrate compliance with IEC-601-1 (including its subparagraphs) Electro-Medical Equipment Safety Standard. The biocompatibility testing of the patient contact material showed that the material is safe for use. Performance testing to EC 11 standard demonstrates performance equivalent to marketed ECG systems. This testing demonstrates that the PRIME ECG System meets electrical and environmental safety standards for safe use.

G. Conclusions

Meridian Medical Technologies has demonstrated through its testing that the PRIME ECG is equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 6 2002

Mr. Jamil F. LaHam
General Manager, Cardiopulmonary Systems
Meridian Medical Technologies, Ltd.
10240 Old Columbia Road
Columbia, MD 21046

Re: K012414
Trade/Device Name: Electrocardiograph
Trade Name: PRIME ECG
Regulation Number: 21 CFR 870.2340
Regulatory Class: Class II (two)
Product Code: 74 DPS
Dated: December 4, 2001
Received: December 6, 2001

Dear Mr. LaHam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012414

Device: PRIME ECG ™ System

Indications for Use:

The PRIME ECG System is intended for the recording of electrocardiographic signals from the body surface.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012414